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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,821	12/07/2001	Hyun-Soo Kim	3267/FLK/(032878-00052)	9666

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,821	KIM ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific pharmaceutically acceptable excipients disclosed, does not reasonably provide enablement for pharmaceutically acceptable excipients or water soluble excipients in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to a tablet which disintegrates in 60 seconds and method of preparing the same consisting essentially of a therapeutic agent, spray-dried mannitol, crospovidone and a pharmaceutically acceptable excipients.

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record appears to use similar excipients but according the Specification does not result in tablets having the same properties as the present invention. As such, it appears that predictability in the art appears to be low.

The amount of direction or guidance present and the presence or absence of working examples:

The specification, in light of the enumerous possible pharmaceutically acceptable excipients, provides relatively few examples of pharmaceutically acceptable excipients and tablet formulations.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad to the extent that there is no indication as to the scope of pharmaceutically acceptable excipients. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims, i.e. determine what other pharmaceutically acceptable excipients will and will not result in a tablet which disintegrates within 60 seconds.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that the invention is limited to tablets which contain a pharmacologically active ingredient, spray-dried mannitol and crospovidone. However, the claims are not limited to the same. The claim in fact requires one or more excipients. There is nothing in the claim which distinguishes excipient from disintegrant. Even if it the same could be surmised from a reading of the claim, Applicant has provided no evidence that any excipient will not effect disintegration time, i.e. by acting to prolong disintegration time or prevent the table from disintegrating within the required 60 seconds. See In re Knowlton, 183 USPQ 33, 37 (CCPA 1974); In re Wiseman, 201 USPQ 658 (CCPA 1979).

Applicant argues that the excipients play no role in providng the 60 second disintegration time, however, as indicated above the claim does not define "excipients". In any case, it is not

an issue of whether the excipient plays a role in providing the 60 second disintegration time. The issue is that one of ordinary skill in the art has to choose from numerous excipients and must test whether a given excipient will extend the disintegration time past or prevent the tablet from disintegrating within the 60 second requirement. Thus, undue experimentation would be required.

Finally, in responding the 35 USC 112, second paragraph rejection relative to essential subject matter. Applicant has argued that the lack of water-insoluble matter and lack of friability are inherent. This can only be the case if the excipient chosen in combination with the other components results in a tablet having said properties. Applicant has not shown that by simply looking at a given excipient one of ordinary skill in the art can conclude that when combined with the other ingredients that the resultant tablet will have said properties. As such, one of ordinary skill in the art would be required to do undue experimentation in order to determine whether a given excipient when combined with the other ingredients will result in a tablet which when disintegrated in the mouth leaves no water-insoluble residue and will have sufficient hardness so as to lack friability.

Claim 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: does not leave significant amounts of water-insoluble matter and is having a hardness such that it is not friable during handling or shipment (Pg. 3, lines 10-16, Pg. 7, lines 24,25, Pg. 8, lines 1).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Claim 4 still does not indicate that effective amounts of spray dried-mannitol and crospovidone are present in amounts sufficient to cause disintegration of the tablet within 60 seconds. The amendment to the preamble is insufficient as it merely recites intended use in claim 4 and "effective amount" in claim 1 does not indicate that the effective amount is sufficient to cause disintegration of the tablet in the oral cavity within 60 seconds. The body of the claim needs to indicate said limitation. Applicant has provided no evidence that any excipient as set forth in claim will inherently result in a tablet with no residue of insolubles. Applicant has provided no evidence that including any excipient or even any water-soluble excipient will result in a tablet having a hardness such that it is not friable. As such, Applicant has not shown that the lack of insoluble residue and requisite hardness are inherent in the claimed invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. See MPEP sections 2171, 2172. Evidence that claims 1-4 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the reply filed 10/14/2004. In that paper, applicant has stated "applicant's invention is limited to tablets which contain a pharmacologically active ingredient, spry-dried mannitol and crospovidone", and this statement indicates that the invention is different from what is defined in the claim(s) because the claims permit additional component by use of the transitional phrase "consisting essentially of" and require the presence of excipients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/78292 in view of Serpelloni et al. (US Pat. 5,573,777).

WO 00/79292 discloses that a quickly disintegrating solid preparation comprising an active ingredient, such as acetaminophen, scopolamine, famotidine or meclizine, D-mannitol with a mean particle diameter of 30 micrometers to 300 micrometers, crospovidone and a cellulose compound, such as crystalline cellulose, powder cellulose, low substituted hydroxypropyl cellulose and carmellose (Pg. 2, lines 22-24, Pg. 3, lines 10-19, Pg. 5, lines 3-29, Pgs. 6, 7, Pg. 8, lines 1-7;Column 2, lines 24-27, 56-68, Column 3, lines 1-5, Column 4, lines 21-68, Column 5, Column 6, lines 1-18). It is disclosed that the time required for intraoral disintegration is preferably about 5 to about 60 seconds and that the tablet hardness is preferably about 10 to 150 N, and, thus, can be used by patients, aged people and children who have difficulty swallowing medicine and is excellent in long-term storage and stability (Pg. 14, lines 1-21;Column 10, lines 8-43). The cites to column and line numbers refer to US Patent 6,740,339 which is the 371 of WO 00/79292.

Serpelloni et al. discloses mannitol which is prepared by atomizing an aqueous solution of mannitol and granulating the atomized powder where the mannitol has a mean diameter of 135 microns with approximately 86% of the particles having a size greater than 100 microns, moderate and not excessive friability, good ability to flow, a very high rate of solubilization of 26 seconds and forms tablets having a hardness of 78 N (Column 10, lines 1-49, Column 12, lines 40-63).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of spray-dried mannitol of which at least 80% has an average particle size over 100 micrometers in combination with crospovidone. However, the prior art amply suggests the same as the prior discloses the use of mannitol in combination with crospovidone in a tablet which disintegrates in less than 60 seconds and discloses a mannitol having properties which fall within the scope of the claimed mannitol. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the Serpelloni et al. mannitol would be suitable for use in the WO 00/78292 product and that the product would be suitable for persons who have difficulty in swallowing solid medications.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
May 13, 2005

S. MARK CLARDY
PATENT EXAMINER
GROUP 1200
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